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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,599	11/29/2001	Masayasu Ogushi	216644US0	2699

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EXAMINER	
AUGHENBAUGH, WALTER	

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,599	OGUSHI ET AL.	
	Examiner	Art Unit	
	Walter B Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-11 and 13-16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claims 1, 2 and 8 made in the Amendment filed January 23, 2004 (Amdt. A) have been received and considered by Examiner.

2. The amendments made in page 6 of the specification have been received and considered by Examiner.

3. The cancellation of claims 3-7 and 12 in Amdt. A has been acknowledged by Examiner.

4. New claims 13-16 presented in Amdt. A have been received and considered by Examiner.

Election/Restrictions

5. Newly submitted claim 16 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions II (claim 16) and I (claims 1, 2, 8-11 and 13-15) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process such as injection molding.

6. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim16 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

WITHDRAWN REJECTIONS

7. The 35 U.S.C. 112 rejection of claims 1 and 2 made of record in paragraph 2 of Paper 8 has been withdrawn due to Applicant's amendments in claims 1 and 2 in Amdt. A.

8. The 35 U.S.C. 103 rejections of claims 1, 2 and 8-11 made of record in paragraphs 4, 5 and 7 of Paper 8 have been withdrawn due to Applicant's amendments in claim 1 in Amdt. A.

9. The 35 U.S.C. 103 rejections of claims 3-7 and 12 made of record in paragraphs 4-6 of Paper 8 have been withdrawn due to Applicant's cancellation of claims 3-7 and 12 in Amdt. A.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 8 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahmed et al.

In regard to claim 1, Ahmed et al. teach medical devices (col. 1, lines 40-48) and more specifically medical tubing (col. 16, lines 15-19) (and therefore a medical tube) obtained by subjecting a resin composition comprising a hydrogenated styrene-isoprene-styrene block copolymer (col. 13, lines 57-64, col. 14, lines 23-26, 43-45 and 54-64, col. 16, lines 64-66 and col. 22, lines 43-54) and a polypropylene that is represented by the name "TAFMER P0480" (col. 17, lines 13-16, col. 22, lines 43-54 and Example 18 in Table 4 at lines 1-24 of col. 23) to

extrusion molding (col. 15, lines 58-62 and col. 16, lines 2-13). Ahmed et al. teach that the tube has a storage modulus of less than $3*10^9$ dynes/cm^2 at 24°C (col. 15, lines 37-41), a range that encompasses the claimed storage modulus range of $5.0*10^7$ dynes/cm^2 to $8.0*10^8$ dynes/cm^2 at 25°C, and also teaches that Example 18 has a storage modulus of $8.12*10^7$ dynes/cm^2 at 24°C (Example 18 in Table 4 at lines 1-24 of col. 23), a value that falls within the claimed storage modulus range. Ahmed et al. teach that the weight ratio of the polypropylene to the hydrogenated styrene-isoprene-styrene block copolymer is 25/75 (col. 22, lines 43-54 and Example 18 in Table 4 at lines 1-24 of col. 23), a ratio that falls within the claimed ratio range of 20/80 to 40/60. Since Ahmed et al. teach all of the structural and compositional limitations claimed in claim 1, the tube necessarily has a ratio of the storage modulus in the extrusion direction to a storage modulus in the circumferential direction of not more than 1.3 at 25°C. The term "endotracheal" in the phrase "endotracheal tube" is an intended use recitation that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). Note that no structure is claimed which limits the claimed tube to solely an endotracheal tube. The recitations "obtained by subjecting" and "to extrusion-molding" are method limitations that have been given little patentable weight since the method of forming the tube is not germane to the issue of patentability of the tube itself. Note that the recitations "as a styrenic elastomer" and "as a polyolefin" do not further limit the composition recited by the phrase "a hydrogenated styrene-isoprene-styrene block copolymer" or the composition recited by the term "polypropylene".

In regard to claim 8, Ahmed et al. teach that the hydrogenated styrene-isoprene-styrene block copolymer comprises a styrenic polymer block and that the content of the styrenic polymer block is 30% by weight (col. 16, lines 64-66), a value that falls within the claimed range of 10 to 40% by weight. In regard to claim 15, Ahmed et al. teach that the hydrogenated styrene-isoprene-styrene block copolymer comprises a hydrogenated polyisoprene block made of polyisoprene (col. 14, lines 43-44 and col. 16, lines 64-66) and that the polyisoprene block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the polyisoprene are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of "not less than 70%".

Claim Rejections - 35 USC § 103

12. Claims 2, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Sterling.

Ahmed et al. teach the tube as discussed above. Ahmed et al. teach that blow molding is a suitable method of forming the composition into an article (col. 15, line 64-col. 16, line 10). In regard to claim 2, Ahmed et al. fail to teach that the tube is provided with a cuff formed from the resin composition comprising a styrenic elastomer and a polyolefin on the outer peripheral surface of the tube, that the cuff has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 25°C and that the resin composition of the cuff has a melt tension of not less than 1g at 230°C. Sterling, however, discloses an endotracheal tube (item 33) having a shaft (item 34) and a cuff (item 41) that is formed on the outer peripheral surface of the tube that are both formed from a blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene (col. 7, lines 1-4 and 27-31, col. 15, lines 17-36 and 52-60 and Fig. 6 and 15). Sterling discloses that the

blend comprising styrene-ethylene-butylene-styrene block copolymer and polypropylene can undergo conventional blow molding techniques (col.14, line 58-col. 15, line 7). Therefore, one of ordinary skill in the art would have recognized to have blow molded the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that is on the outer peripheral surface of the endotracheal tube that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blow molded the resin composition comprising a styrenic elastomer and a polyolefin taught by Ahmed et al. which has a storage modulus of not more than $5.0*10^8$ dynes/cm^2 at 24°C into a cuff in order to form the medical tube of Ahmed et al. into an endotracheal tube since it is known to form an endotracheal tube having a shaft and a blow molded cuff that is on the outer peripheral surface of the endotracheal tube that are both formed from a blend comprising a styrenic block copolymer and a polyolefin as taught by Sterling.

The recitations "obtained by subjecting" and "to blow-molding" are method limitations that have been given little patentable weight since the method of forming the cuff is not germane to the issue of patentability of the cuff itself.

In regard to the claimed melt tension of the resin composition of the cuff of not less than 1g at 230°C, the selection of polymeric compositions having suitable melt tension for the particular desired end use would have been obvious to one of ordinary skill in the art at the time

the invention was made, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regard to claims 10 and 11, Ahmed et al. teach that additives such as fillers can be included in the resin composition (col. 15, lines 50-58). Ahmed et al. fail to teach that the filler is present in an amount of 5 to 20% by weight (as claimed in claim 10) and that the filler is one of the chemical species claimed in claim 11. Sterling, however, discloses that the block copolymer/polypropylene blend contains up to 25% polystyrene as an additive (col. 4, lines 54-55) that improves the rheological properties of the blend (col. 11, lines 5-6). Sterling discloses that the polymeric components (i.e. the elastomeric block copolymer, the polypropylene and the polystyrene additive) are introduced as a mixture in pellet form (col. 11, lines 26-32), which Examiner interprets to be structurally equivalent to beads as claimed. Therefore, one of ordinary skill in the art would have recognized to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition of Ahmed et al. in order to improve the rheological properties of the blend as taught by Sterling.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added crosslinked polystyrene beads in an amount of 5 to 20% by weight to the composition of Ahmed et al. in order to improve the rheological properties of the blend as taught by Sterling.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Ikematu et al.

Ahmed et al. teach the tube as discussed above. Ahmed et al. fail to teach that the resin composition of the tube comprises at least one lubricant selected from the group consisting of a fatty acid amide lubricant and a fatty acid monoglyceride lubricant in an amount of 0.05 to 0.5% by weight. Ikematu et al., however, disclose a styrenic block copolymer (col. 7, lines 38-46) used as a medical instrument material (col. 13, lines 21-28) that is formed into a tube (col. 13, lines 35-36). Ikematu et al. disclose that the composition comprises a lubricant such as fatty acid amide in an amount of 0.01 to 2 parts by weight per 100 parts of resin (col. 12, lines 3-24), an amount that overlaps with the claimed range of 0.05 to 0.5%. Therefore, one of ordinary skill in the art would have recognized to have added fatty acid amide to the polymeric composition of Ahmed et al. in order to lower the coefficient of friction of the tube of Ahmed et al. with respect to any opposing surface (i.e. lubricate the tube) since it is known to add lubricants such as fatty acid amide to tubes used in medical applications as taught by Ikematu et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added fatty acid amide to the polymeric composition of Ahmed et al. in order to lower the coefficient of friction of the tube of Ahmed et al. with respect to any opposing surface (i.e. lubricate the tube) since it is known to add lubricants such as fatty acid amide to tubes used in medical applications as taught by Ikematu et al.

14. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. in view of Ishii et al.

In regard to claim 13, Ahmed et al. teach the tube as discussed above. Furthermore, Ahmed et al. teach that the hydrogenated styrene-isoprene-styrene block copolymer comprises a hydrogenated polyisoprene block made of polyisoprene (col. 14, lines 43-44 and col. 16, lines

64-66) and that the polyisoprene block is hydrogenated such that at least 80% of the carbon-carbon double bonds of the polyisoprene are hydrogenated (col. 14, lines 54-64), a range that overlaps with the claimed range of "not less than 70%". Ahmed et al. fail to teach that the hydrogenated polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mol. Ishii et al., however, teach a composition for use in medical devices such as catheter tubes having a suitable flexibility and transparency for medical applications (paragraphs 1 and 2 of Detailed Description section of translation of JP 10-067894) Ishii et al. teach that the composition comprises a polypropylene-block copolymer blend comprising a block copolymer having a polyisoprene block that has a 1,2-bond and 3,4-bond content of 10 to 75% by mole (lines 1-3 of paragraph 6). Therefore, one of ordinary skill in the art would have recognized to have polymerized the polyisoprene block of Ahmed et al. such that the polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al. (paragraphs 1, 2 and 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have polymerized the polyisoprene block of Ahmed et al. such that the polyisoprene block has a 1,2-bond and 3,4-bond content of 10 to 75% by mole in order to form a tube having a suitable flexibility and transparency for medical applications as taught by Ishii et al.

In regard to claim 14, Applicant defines the "1,2-bond and 3,4-bond content" as the "content of vinyl bonds" on page 6, lines 2-3 of the specification. Therefore, claim 14 is identical to the first 4 lines of claim 13 and therefore stands rejected under 35 U.S.C. 103(a) over Ahmed et al. in view of Ishii et al. for the reasons provided above in regard to claim 13.

ANSWERS TO APPLICANT'S ARGUMENTS

15. Applicant's arguments on pages 6-7 of Amdt. A regarding the 35 U.S.C. 103 rejection of claim 1 over Ahmed et al. have been fully considered but are not persuasive. Ahmed et al. teach the limitations Applicant has cited in the first full paragraph of page 7 of Amdt. A as made of record in the 35 U.S.C. 102 rejection of claim 1 as anticipated by Ahmed et al. that is made of record in this Office Action. Applicant's statement that "if Ahmed's ethylene interpolymer is used in place of the polypropylene, an endotracheal tube with excellent transparency cannot be obtained" is unsupported, and the limitation that the tube have "excellent transparency", upon which Applicant bases this argument, is not stated in the claim.

16. Applicant's argument on page 7 of Amdt. A regarding the 35 U.S.C. 103 rejection of claim 2 over Ahmed et al. in view of Sterling has been fully considered but is not persuasive. Applicant argues that "Sterling fails to suggest the hydrogenated styrene-isoprene-styrene block copolymer" and suggests that the "hydrogenated styrene-isoprene-styrene block copolymer" is deficient from Ahmed et al. Ahmed et al., however, teach the hydrogenated styrene-isoprene-styrene block copolymer as claimed in claim 1 as made of record in the 35 U.S.C. 102 rejection of claim 1 as anticipated by Ahmed et al. that is made of record in this Office Action, so Sterling is not relied upon to "remedy" this alleged "deficienc[y]".

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
04/06/04 WBA

HAROLD PYON
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1772

4/12/04